UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, *ex rel.* JAMES ALLEN, Plaintiff, v. GUIDANT LLC, formerly doing business as GUIDANT CORPORATION, GUIDANT SALES LLC, formerly doing business as GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., and BOSTON SCIENTIFIC CORPORATION, Defendants.	)	Civ. No.: 11-cv-22 (DWF/AJB)

STATE OF NEW YORK)
) ss.:
COUNTY OF ERIE)

JAMES ALLEN, being duly sworn, deposes and states:

1. I am the Relator in the above referenced action and, as such, I am fully familiar with the matters set forth herein.

2. I make this affidavit in opposition to the Defendants' Motion to Dismiss my False Claims Act ("FCA") qui tam Amended Complaint, which was filed on July 22, 2010. This FCA action was originally filed under seal in the United States District Court for the Western District of New York on July 10, 2008 (with the attorneys for the United States of America obtained orders extending the seal until March 29, 2010).

3. Contrary to defendants' assertions, and as discussed herein, I have direct and independent knowledge of the allegations set forth in the Amended Complaint, namely of the defective nature of the Ventak Prizm 2DR 1861 defibrillators manufactured after April 16, 2002 and of the Defendants' deception and efforts to hide their wrongdoing and deceive the public and the United States Government about the safety of their devices.

PERSONAL BACKGROUND

4. I was born on October 27, 1946.

5. After graduating high school, I volunteered and enlisted in the United States Marine Corp on May 25, 1966. I served in Vietnam from December 1966 until January 1968.

6. During the time I was in Vietnam, I was in combat for 13 months except when I sustained injuries which required medical treatment and care on the hospital ship USS Repose.

7. As a result of my combat service, and wounds I received during it, I was awarded three Purple Hearts. The first was awarded when I was struck by shrapnel in both legs. I received treatment at the hospital ship to remove the shrapnel. After some healing time on the ship, I was then sent back to combat, and, in hand-to-hand combat, I was struck with a rifle butt in the face resulting in the loss of 7 teeth and other facial injuries. After treatment on the hospital ship, I was again sent back into combat. The third Purple Heart was awarded when I was wounded from a mine blast, resulting in a concussion and temporary loss of hearing again requiring treatment on the hospital ship. During my tour in Vietnam, I was also sprayed with the chemical compound Agent Orange.

8. I proudly served my country. When I enlisted I was a private and, when I was honorably discharged from the service, I was an E-5 Sergeant – a rank that normally took in excess of 15 years to achieve.

9. As a result of my military service, I am now considered 100% permanently disabled by the United States government.

10. After the service, I supported myself and my family as a self-employed businessman through various enterprises. My last endeavor was a high-end retail dry cleaning business which I had to close in 2007 when I was no longer physically able to run it.

HEART CONDITION PRIOR TO AUGUST 27, 2002

11. I suffered my first heart attack in 1989. My second heart attack occurred in 1995. In 1999, I had quadruple by-pass surgery.

12. On August 23, 2002, I stopped breathing in bed. My wife gave me CPR. I was rushed to the hospital. My wife and I were told that I had suffered a fatal arrhythmia and that if it wasn't for the quick response of my wife and the first responders to my home, I would have died.

AUGUST 27, 2002 SURGERY

13. On August 27, 2002, I was implanted with a Prizm 2DR defibrillator unit. The decision to implant the unit was made by my doctors with the consent of my wife since, at that time, I was not in any condition to make any decision. The surgery was performed at Buffalo General Hospital in Buffalo, New York.

14. From subsequent documentation obtained from Guidant Corporation, I learned that the device implanted in me was manufactured and/or assembled at Guidant's Ireland (Clonmel Tipperary) facility on June 13, 2002.

DECEMBER 2, 2002 DEVICE FAILURE

15. On December 2, 2002, my Prizm device malfunctioned for the first time.

16. I was outside in the middle of the road when the device malfunctioned sending seven different shocks of up to 750 volts into my heart. The shocks were severe, caused unbelievable pain, and ultimately rendered me unconscious.

17. Fortunately, a school bus driver passing by stopped and immediately radioed for assistance. I was taken by ambulance and regained consciousness on the way to the hospital.

18. The treating physicians contacted Guidant for their assistance.

19. A Guidant salesman, who I believe was James Davis, came to the hospital and interrogated the device.

20. It turned out that the device malfunctioned in that it read a normal SVT (Supraventricular tachycardia) as a deadly VT (Ventricular tachycardia) and thus improperly delivered the shocks to my heart.

21. I heard the conversations between Mr. Davis and the physicians. I specifically remember Dr. Jeanne Basior questioning Mr. Davis about the functioning of the device and expressing the opinion that the device had malfunctioned. Dr. Basior also questioned the device's ability to provide therapy shocking in the event of an actual event.

22. Mr. Davis assured the physicians the unit only needed a slight adjustment, otherwise it was functioning fine.

23. This was the first time that I became concerned about my device and how it was functioning.

THE 2003 DEVICE FAILURE

24. The second time I became aware that the device was malfunctioning was in 2003 (though I cannot recall the precise date). Again, the device unnecessarily and improperly "storm shocked" my heart. The pain was intense and caused me to fall down a flight of stairs.

25. This second malfunction of the device scared me, and I was concerned for my life.

2003-2004 EFFORTS

26. After the second malfunction, I knew that the device was not what it was advertised to be. My belief was further supported by the fact that my physicians could not explain why my device was malfunctioning. Accordingly, in order to try to stay alive and protect my health, I endeavored to learn everything I could about the Prizm 2 DR defibrillator, and its manufacturer, Guidant.

27. I checked out adverse event reports which are filed pursuant to FDA regulations and/or rules. In early 2004, I came across an adverse event report (#2124215-2004 dated February 2, 2004) which listed Richard Roy as the manufacturer contact person. The report further stated that Guidant became aware of an electrical shorting issue with the Prizm units in 2002, but that Guidant subsequently obtained FDA approval and implemented steps in

manufacturing to mitigate this issue. The report specifically stated that: "No issues of this nature have been identified since these manufacturing enhancements have been implemented."

28. Upon reviewing the report, I became very alarmed since my unit was implanted in 2002, and based upon the unit's previous malfunctions, I was concerned my unit had the same defects (contrary to Guidant's statements that the "manufacturing enhancements" had fixed the problem).

29. I telephoned Guidant and I was informed that Mr. Roy was indeed the head of that department and was the manufacturer's contact person. Guidant employees initially refused to permit me to speak to Mr. Roy. However, I persisted and, after much effort, I was able to speak with Mr. Roy, who informed me that Guidant had obtained all necessary FDA approval for the changes and that my unit was manufactured after the changes were made.

30. Based on my experiences, though, I was not convinced and I continued my efforts to find out the truth about the Prizm defibrillators.[1]

GUIDANT'S FRAUDULENT MANIPULATION OF DATA REPORTED TO THE GOVERNMENT

31. As I became more knowledgeable about the device in my body, I learned that Guidant was legally obligated to report adverse events involving their devices. This would include the malfunction of my device in December, 2002.

[1] Guidant, almost two years after I filed my original FCA complaint, admitted in a Plea Agreement (filed March 11, 2010 in case 10-mj-67) to filing a false and misleading statement in a material respect when it stated in its August 19, 2003 periodic post-approval report that the November 13, 2002 changes to correct a device flaw that was known as arcing did not affect the safety and efficacy of the device. This simply confirms my initial impression that Mr. Roy's statement in his report and his oral statements to me that Guidant obtained FDA approval for the changes were lies.

32. Given my doctor's statements of concern regarding my Prizm 2DR defibrillator, I was curious as to what Guidant reported in the adverse event report concerning the malfunctioning of my device. However, after I searched, I found there had been no adverse event report filed by Guidant concerning the malfunction of my device on December 2, 2002. Guidant had concealed this malfunction. Guidant continued to maintain that this device had been "fixed" by some "manufacturing enhancement" which was instituted before my device was manufactured. If Guidant had reported the malfunction of my device, this would have been evidence that the "manufacturing enhancement" had not in fact "fixed" the problem.

33. Upon information and belief, this was a pattern of Guidant. The company made the Prizm 2DR devices manufactured after April, 2002 appear to function better by simply failing to report malfunctions. This was a critical revelation for me as I considered my potential FCA. I now believe that Guidant had manipulated data upon which the FDA and others would make decisions, including whether these devices should continue to be sold.

34. I am also aware from the limited discovery that has taken place in this action that Guidant will attempt to defend against the allegations in both the Amended Complaint and the Government's Complaint in Intervention by claiming that the defects in the Prizm 2DR were "fixed" in April, 2002. In another words, Guidant continues to perpetrate this fraud even to the present day, in this very Court.

2005 EVENTS

35. There were several significant events that occurred in 2005 relating to the defibrillator in my chest and my interactions with Guidant.

36. By 2005, I was petrified the device would fail by either not working when I had a heart attack or it would unnecessarily shock me causing further heart damage and possibly death.

37. I became aware of newspapers articles in and after May 2005 and a Guidant Urgent Medical Device Safety Information and Corrective Action issued on June 17, 2005. But the message in both of these publications was that my device was fine, and that the problem had been "fixed" in April, 2002.

38. On August 8, 2005, shortly after Guidant issued its Information and Corrective Action, my physician, Dr. Robert Gatewood, sent me a letter advising me that he was informed my device had been recalled. Given what I had read about Guidant's public assertions that my device was fine, I was a little confused about this statement from my doctor.

39. By that time, regardless of a recall, I knew that I wanted the Prizm device out of my chest and replaced by a new device from another company, and I began making arrangements to do just that. I knew the device had a tendency to malfunction.

40. I also made many calls to Guidant to speak with Mr. Roy who, with the exception of the one phone call with me in 2004, refused to speak with me. Due to my persistence, Guidant eventually permitted me to speak to Daniel J. Tich, Manager, Product Performance Communications, Reliability Assurance Guidant Corporation ("Mr. Tich").

41. During my discussions with Mr. Tich, I expressed my concerns based on my personal experiences and questioned Mr. Tich about various aspects of the Prizm devices and Guidant's actions relating to them. Attached as Exhibit A are copies of Mr. Tich's August 19, September 6, October 12, October 27 2005, as well as March 7, and March 15, 2006 letters in

reply to my inquiries.[2] Attached as Exhibit B is my October 15, 2005 letter to Mr. Tich. (¶¶ 82-97 of the Amended Complaint also describe in detail part of Mr. Tich's response to my inquiries).

42. During this time period, Guidant also actively participated in causing the cancellation of my surgery to have the defective Prizm device replaced and a new device implanted.

43. Guidant's James Davis contacted my surgeon, Dr. Subhajit Datta, and informed him that my Prizm unit had not been recalled, that if he implanted another unit my insurance company may not pay for it, and that I would file bankruptcy and not pay Dr. Datta.[3]

44. This outrageous conduct by Guidant not only actively interfered with my medical treatment for my heart condition, but also jeopardized my insurance coverage and personally insulted me.[4]

45. After great effort and distress, I was able to locate another physician who agreed to replace my Guidant unit and my insurance company paid for the medical expenses.

46. Consistent with Guidant's pattern of concealment nothing about the "elective" explanation of my device was reported by Guidant to the FDA. At this point, I had had enough. It was quite clear that Guidant would go to great lengths to cover up the problems with their device, and that the company's public statements that the devices were fine were false.

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[2] As set forth in the Amended Complaint (¶ 88), since the information disclosed by Mr. Tich in his August 19, 2005 letter was not consistent with the information Guidant had publicly disclosed, I forwarded a copy of that letter to the FDA within days of receiving it.

[3] Although I served in the military during a combat time, I had private insurance and did not receive any VA benefits associated with the surgeries discussed in this affidavit.

MY FEBRUARY 7, 2006 DISCLOSURE TO FDA AND FDA RELEASE OF MY INFORMATION

47. By January 2006, spurred by my personal experiences, I had discovered that the 11,000 plus Prizm 2DR devices manufactured between April 16, 2002 and November 13, 2002 had a significant failure rate.

48. By the end of 2005, I had personal experience with a Prizm 2DR defibrillator which lead me to believe it was defective. I personally heard a Guidant salesman in December, 2002, tell my doctor that the device which had just malfunctioned was fine. I personally learned through experience that Guidant was concealing malfunctions by failing to report adverse events. Guidant lied to me directly when I tried to get their defective device removed from my body. Guidant was so desperate to conceal the defects that they tried to prevent my operation. I also knew that Guidant was telling me and others that these devices were perfectly fine when they were not.

49. On or about February 2, 2006, I voluntarily sent the FDA 27 pages of information, alerting the FDA to the multiple failures of the Prizm 1861 defibrillators manufactured between April 16, 2002 and November 13, 2002. My 27 page submission to the FDA is attached as Exhibit C.

50. Based on my submission, the FDA published an adverse event report on February 7, 2006. A copy of the adverse event report, number MW 1037978, is attached as Exhibit D.

51. The Model Number and Event Description of my adverse event report reads:

(..continued)

[4] Mr. Tich's October 12, 2005 letter weakly attempted to justify Guidant's inexcusable interference with my medical care in having my Guidant unit replaced.

> Rptr has uncovered with respect to the Guidant Ventak Prizm 2 DR 1861 devices, manufactured 04/16/2002 – 11/13/2002. (not recalled) the 11,000 devices have the highest rate of failure of any of the Guidant devices manufactured to date; in excess of (5%) percent over 600+ adverse events have not been reported. The devices' capacitors, high voltage line insulation and the batteries are and will continue to fail. The capacitors are under size, the batteries are failing 25% to 40% faster than the 7 years stated by Guidant. They can fail in a 3 hour period. The insulation is being destroyed by body fluids, this starts to occur 10 months after the implant and the failures show up in the second half of the device longevity.

52. There was no public disclosure of the facts contained in my adverse event report prior to the FDA release of such information.

THE ALLEGATIONS AT ISSUE IN THIS ACTION ARE DIFFERENT THAN THOSE WHICH WERE PREVIOUSLY DISCLOSED AND/OR LITIGATED

53. It is my understanding that the Defendants are claiming in their motion that my FCA action is based on the well-publicized events of 2005 (namely the 2005 New York Times articles and a July 2005 FDA release) as well as prior complaints relating to Guidant's devices, specifically the complaint in my personal action against Guidant and the Multi-District Litigation ("MDL") Complaint that was before this Court. That is simply not the case.

54. The New York Times articles were related to defects in devices manufactured prior to April 16, 2002. The articles quoted Guidant officials who repeatedly stated that the "flaw" was corrected, that Guidant complied with and obtained FDA approval for the changes, and that the "problem" had not happened in any devices made after April 2002.

55. The July 2005 FDA News Release similarly dealt only with the recall of Prizm 2DR devices manufactured before April 16, 2002.

56. I personally knew that these statements by Guidant were false and misleading. How did I know that Guidant was lying? Because my heart had been improperly electrocuted on two separate occasions by their defective device, which admittedly was manufactured after April 2002. Moreover, I bore personal witness to Guidant's deceitful conduct when they attempted to prevent me from obtaining surgery to remove the defective Prism device and when they continually stone-walled my attempts to get answers from corporate executives.

57. Moreover, the allegations in my personal complaint and the MDL complaint concerning devices manufactured after April 16, 2002 were based, in part, on my personal experiences and knowledge – which also form the basis of the allegations in the Amended Complaint.

58. Indeed, any information relating to the discovery that occurred in the MDL has been subject to a protective order and has never been made available to me. I made many attempts to obtain information about the MDL, but was informed no information could be released. Even in this lawsuit, Defendants refused to permit my attorneys and me access to the MDL litigation materials and made a motion to stay discovery to prevent me from gaining access to that material. Hence, in preparing both the original FCA complaint and the Amended Complaint, neither I nor my attorneys had any access to discovery materials from the MDL.

CONCLUSION

59. Using my personal experience and knowledge as a base, I have continued collecting information and documents that confirm and support what I personally knew to be the case – that the Ventak Prizm 2DR 1861 defibrillators manufactured after April 16, 2002 were

defective and deadly, and that defendants would go to great lengths to hide that fact from other individuals who had the devices implanted, from physicians, from the public and from the FDA.

60. The Defendants are now attempting to use the fact that I acted on my personal experiences and conducted further independent research and obtained additional non-public documents against me. The fact remains, though, that the allegations in the Amended Complaint do arise from my personal knowledge and experience.

61. On July 10, 2008, when I filed the original FCA Complaint in camera and under seal in the United States District Court Western District of New York, I personally knew from my own experiences that my device (manufactured after April 16, 2002) had twice malfunctioned, that Guidant actively interfered with my efforts to have the device replaced, that Guidant was claiming devices manufactured after April 16, 2002 were not dangerous or defective, and that Guidant never filed any adverse event reports about the malfunctions of my device.

62. As demonstrated above, I am not some random, disinterested individual who stumbled upon a newspaper article or court filing and created a lawsuit on the back of some other's person's efforts. I have intimate direct and independent personal knowledge of the defective nature of the devices at issue in this lawsuit, and I have direct and independent personal knowledge of the heinous acts of the Defendants – who attempted to deceive me about the safety of their device and could have cost me my life by thwarting my initial efforts to have their deadly device replaced.

63. The above is true to the best of my knowledge.

/s/ James Allen
James Allen

Sworn to before me this
21 st day of December 2011

/s/ James I. Meyers
Notary Public

Qualified in Erie County
My Commission Expires: 12/31/14